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10/727,151	12/02/2003	David K. Swanson	03-0515 (US01)	5305

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,151	SWANSON, DAVID K.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,17,19,20 and 32-42* is/are pending in the application.

4a) Of the above claim(s) *38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17,19,20,31-37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau (U.S. Patent 4,685,466) in view of Baker et al. (U.S. Patent 6,228,082).

Regarding claims 14 and 32, Rau discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5) configured to emit stimulation energy that is applied to tissue (see abstract, col. 3:3-15), wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and means (collectively "suction cup" 2 and "vacuum line" 4, see col. 4:46-52 and figures 4 and 5), associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure. Although Rau discloses the plurality of needle electrodes (needle electrode having pointed tip 1) are

spaced approximately 0.5 mm apart (see col. 3:64-67), Rau is silent as to the diameter of the needle electrode. Baker et al. disclose an electrosurgical device having needle electrodes and teach the "needle electrode is an insulated acupuncture sized needle having a diameter in the range of about 0.05 to about 2.0 mm, preferably less than 1 mm in diameter" (see col. 2:66 - col. 3:2) and further teach a small diameter of 0.05 mm to about 2.0 mm, preferably less than 1.0 mm minimizes tissue trauma (see col. 6:43-45). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rau, as taught by Baker et al., to use needle electrodes having a small diameter in the range of 0.05 mm to 2.0 mm in order to minimize tissue trauma.

Claims 17, 19, 20 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (U.S. Patent 4,144,890) in view of Baker et al. (U.S. Patent 6,228,082).

Regarding claims 17 and 33, Hess discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode (collectively 21 and 37, see col. 2:31- col. 3:35 and figures 1-7) configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and an anchor (collectively portions defined by 25, 27, 31 and 33 in col. 2:42-55 and figures 1-3 or portions defined by 41-44 in col. 3:9-18 and figures 4-6), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue, see col. 2:12- col. 3:52 in general. Hess is silent as to the diameter of

the electrode. Baker et al. disclose an electrosurgical device having needle electrodes and teach the "needle electrode is an insulated acupuncture sized needle having a diameter in the range of about 0.05 to about 2.0 mm, preferably less than 1 mm in diameter" (see col. 2:66 - col. 3:2) and further teach a small diameter of 0.05 mm to about 2.0 mm, preferably less than 1.0 mm minimizes tissue trauma (see col. 6:43-45). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Baker et al., to use needle electrodes having a small diameter in the range of 0.05 mm to 2.0 mm in order to minimize tissue trauma.

Regarding claims 19 and 20, Hess discloses that the anchor comprises a flexible carrier (elongated element defined by ends 42 and 42) that is non–linear when in the relaxed state, as it has a u-shaped or cup shaped transverse cross-section, see col. 3:9-18 and figures 4-7.

Claims 34-37, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau (U.S. Patent 4,685,466) in view of Franchi (U.S. Patent 5,466,255) in further view of Daddona et al. (U.S. Patent 6,091,975).

Regarding claims 34-36 and 40, Rau discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5) configured to emit stimulation energy that is applied to tissue (see abstract, col. 3:3-15), wherein a size of the tissue

stimulation element is too small to form a transmural myocardial lesion; and a flexible carrier movable ("suction cup" 2, see col. 4:46-52 and figures 4 and 5) between an unstressed state (when no suction/vacuum is applied) and a deflected and stressed state (when suction/vacuum is applied and the tips of the needle electrodes is inserted into the tissue, and since the suction cup is made of a "flexible rubber material," see col. 5:10-12 whenever the suction/vacuum is applied the suction cup is inherent placed in a deflected/stressed state) and including a first end portion (portion of "suction cup" 2 adjacent to "vacuum line" 4, see col. 4:46-52 and figures 4 and 5) that carries the first tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1 adjacent to "vacuum line" 4, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5), a second end portion (portion of "suction cup" 2 opposite the "vacuum line" 4, see col. 4:46-52 and figures 4 and 5) that carries the second tissue stimulation element, in the form of a stimulation electrode (needle electrode having pointed tip 1 opposite the "vacuum line" 4, see col. 4:28-62 and figures 1-6, particularly figures 4 and 5) and an interior portion located between the first and second end portions and configured such that the interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state (although this recitation is intended use it is clearly shown in figures 4 and 5). Rau fails to disclose 1) that the interior portion is curved and 2) a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state. Franchi discloses a stimulation electrode

device and teaches providing the tissue contacting electrically conductive side of the device with a concave surface in order to engage a convex tissue surface and "claws" (9) in order to secure the device to cardiac tissue, see col. 4:15-30 and figures 6-9. Daddona et al. disclose a electrical device for the skin and teach providing the device with a tissue engagement device in the form of a collection of "microprotrusion" barbs (jagged additions to some, i.e. every third electrode 4) in order "to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation" and further secure the device to the skin and as an alternative to pressing the device against the skin by hand, see col. 2, line 18-26 and col. 2 and 3 and figures 1-4. This combination provides a flexible concave suction cup having at least two opposed end stimulation electrodes with a plurality of other stimulation electrodes therebetween wherein some of the interior stimulation electrodes have microprotrusion barbs. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rau, as taught by Franchi, to provide the suction cup of Rau with a concave surface in order to engage a convex tissue surface and "claws" in order to secure the device to cardiac tissue, and as further taught by Daddona et al., to provide the device with a tissue engagement device in the form of a collection of "microprotrusion" barbs uniformly distributed on the electrode tips of the interior in order "to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation" and further secure the device to the skin.

Regarding claims 37 and 42, Rau in view of Franchi in further view of Daddona et al. disclose the claimed invention as the microprotrusion barbs are disposed at the distal tip of the electrodes and have tissue penetrating tips/ends.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rau (U.S. Patent 4,685,466) in view of Franchi (U.S. Patent 5,466,255) in further view of Daddona et al. (U.S. Patent 6,091,975) as applied to claim 34 above, and further in view of Baker et al. (U.S. Patent 6,228,082).

Regarding claim 41, Rau in view of Franchi in further view of Daddona et al. disclose the claimed invention except for the first and second tissue stimulation elements each having a diameter of about 0.5mm to 1.0 mm in diameter. Baker et al. disclose an electrosurgical device having needle electrodes and teach the "needle electrode is an insulated acupuncture sized needle having a diameter in the range of about 0.05 to about 2.0 mm, preferably less than 1 mm in diameter" (see col. 2:66 - col. 3:2) and further teach a small diameter of 0.05 mm to about 2.0 mm, preferably less than 1.0 mm minimizes tissue trauma (see col. 6:43-45). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Baker et al., to use needle electrodes having a small diameter in the range of 0.05 mm to 2.0 mm in order to minimize tissue trauma.

Response to Arguments

Applicant's arguments with respect to claims 14, 17, 19, 20, 32-37 and 40-42 have been considered but are moot in view of the new ground(s) of rejection.

In order to expedite prosecution the examiner would like to make a few comments regarding the claims.

First, Applicant has amended claims 32-34 with the phrase "configured to emit stimulation energy that is applied to tissue." This is not in fact a positive recitation the stimulation elements emit stimulation energy, but merely a functional limitation. Although this amendment is a functional limitation, it has precluded the use of Gadsby as a primary reference for rejecting the claims. However, it should be noted, claims 32-34 do not preclude the examiner from interpreting the stimulation energy to be some form of energy other than electrical energy.

Secondly, if in fact Applicant is attempting to positively recite that the stimulation elements emit stimulation energy, Applicant may find it useful to explicitly claim the source of stimulation energy, which Applicant has not done.

Finally, the above two points are however moot, as Rau clearly discloses that the needle electrodes are in addition to sensing electrodes, used for tissue stimulation in an alternative modality.

This action is made FINAL.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. When responding to this action, Applicant may find reviewing the following U.S. Patents useful: 5,545,207 to Smits et al.; 5,330,525 to Proctor and 4,177,818 to De Pedro.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769